

201-14891

Anh Nguyen

12/10/03 02:34 PM

To: NCIC HPV@EPA

CC:

Subject: HPV submission letter from Paul Mudge

----- Forwarded by Anh Nguyen/DC/USEPA/US on 12/10/2003 02:42 PM -----

janet.marcincavage@nstarch.com on 12/10/2003 01:32:41 PM



To: NCIC OPPT@EPA, Rtk Chem@EPA
cc: paul.mudge@nstarch.com

Subject: HPV submission letter from Paul Mudge

As part of the ICI group and on behalf of ICI Americas, Inc., National Starch and Chemical Company is pleased to submit the revised test plan and revised robust summaries for 2-Propenamide, N-(1,1,3,3-tetramethylbutyl)-(registration number under the U.S. High Production Volume (HPV) Challenge Program (AR-201).

Included in the submission are:

- Revised test plan in WORD 97 format
- Revised robust summaries of available data - in WORD97 format
- Covering letter - pdf format

A copy of the documentation has been sent via certified mail delivery to EPA on 12/10/03.

(See attached file: 4223_03_4-Test Plan Revision.doc) (See attached file: HPV Scanned Cover Letter to EPA 121003Page2.pcx) (See attached file: HPV Scanned Cover Letter to EPA Page1.pcx) (See attached file: IUCLID Data Set-HPV Revision.doc)

If there are any problems please contact Paul Mudge.

Best Regards,

Janet Marcincavage
Product Assurance and Regulatory Affairs
National Starch and Chemical Company

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4223 03 4-Test Plan Revision.doc HPV Scanned Cover Letter to EPA 121003Page2

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HPV Scanned Cover Letter to EPA Page1. IUCLID Data Set-HPV Revision.do

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December 10, 2003

Administrator
Chemical Right-to-Know Program
US EPA
PO Box 1473
Merrifield, VA 22116

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03 DEC 11 AM 10:45

RE: **2-Propenamide, N-(1,1,3,3-tetramethylbutyl)-; CAS # 4223-03-4**

Dear Administrator:

As part of the ICI Group and on behalf of ICI Americas Inc, National Starch and Chemical Company submitted a test plan and robust summaries to the EPA for 2-propenamide, N-(1,1,3,3-tetramethylbutyl)- (CAS No. 4223-03-4) on December 18, 2002. The submission was posted on the ChemRTK HPV Challenge Web site on January 17, 2003 and EPA provided comments on May 8, 2003.

National Starch and Chemical Company is committed to the HPV Challenge Program and propose the following revised test program in response to the valuable comments provided by EPA, Environmental Defense and Animal Protection Organizations.

Test Plan

Physicochemical Properties

The following parameters will be measured:

Melting point (OECD 102), Boiling Point (OECD 103), Vapour pressure (OECD 104), Partition coefficient (OECD 117), Water solubility (OECD 105).

Environmental Fate and Behavior

Hydrolysis (OECD 111), biodegradation (OECD 301B) and transport and distribution (fugacity – by calculation)

Ecological Effects

It is suggested that testing of the physical chemical properties and the fate and behavior in the environment are carried out prior to a decision on the conduct of testing in fish, daphnia and



US EPA
December 10, 2003

algae. These tests will provide information on the environmental compartment of interest and may allow the waiver of testing, at least for the fish species. Should any or all of the tests be required once more data have been generated on the test material, then National Starch and Chemical Company are committed to conducting the testing.

Health Effects

A combined repeat dose/reproduction/developmental study (OECD 422) will be carried out. It is proposed that an acute study is not required as signs of clinical toxicity were detected in the existing single dose in vivo genetic toxicity study. Data from this study will therefore be used to assist in the dose selection for the developmental study, together with a dose range-finding study. This approach will ensure the minimum numbers of animal are sacrificed to fulfill the data requirements.

The original test plan has been up-dated to incorporate the above-mentioned changes and is attached.

EPA requested that the robust summaries be revised to ensure adequacy of available data. This has been done and is also attached.

The submission has been submitted electronically to oppt.ncic@epa.gov and chem.rtk@epa.gov

If you require any more information, please do not hesitate to contact me.

Yours sincerely,

Paul R. Mudge, Ph.D.
Divisional Vice President
Product Assurance and Regulatory Affairs
National Starch and Chemical Company

PRM/jlm